From: Kristi Schroeder 11-05-09 5:57pm p. 10 of 21

To: USPTO

044.P001 <u>Patent</u>

## IN THE CLAIMS

## Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application. Where claims have been amended and/or canceled, such amendments and/or cancellations are done without prejudice and/or waiver and/or disclaimer to the claimed and/or disclosed subject matter, and the applicant and/or Applicant reserves the right to claim this subject matter and/or other disclosed subject matter in a continuing application.

## Listing of Claims:

What is claimed is:

1. (Currently amended) A pharmaceutical composition, comprising:

at least one pharmaceutically active ingredient; and
poly(ethylene sebacate).

wherein said pharmaceutical composition is in the form of different drug delivery systems, wherein said drug delivery systems comprise one or more of the following structures: drug loaded microparticles, microcapsules, nanoparticles, molded implants, coated granules, films, coated tablets, ophthalmic inserts, fibers, ligatures or sutures

Pharmaceutical compositions comprising at least one pharmaceutically active ingredient and biodegradable aliphatic polyesters derived from fatty diacids and fatty diols both with even number of carbon atoms; particularly polyethylene sebaccate which is thermally stable, non-toxic, and metabolized by normal lipid metabolism in the form of different drug delivory systems such as drug loaded microparticles, nanoparticles, molded implants, coated granules, injectable sustained rolease particles, stents, films, matrix tablet, coated tablets, dry syrup, mouth dissolving tablets, microparticles dispersed in gels, taste masked formulation, inserts (ophthalmic), fibers, ligatures and sutures.

044.P001 <u>Patent</u>

2. (Currently amended) The pharmaceutical composition as claimed in claim 1 wherein molecular weight of said poly(ethylene sebacate) is in the range of 3.000 to 30.000 The compositions as claimed in claim 1, wherein the molecular weight of said polyethylene sebaccate is in the range of 3,000 to 30,000.

- The pharmaceutical composition as claimed in claim 1, wherein 3. (Currently amended) said pharmaceutically active ingredient comprises anti-hypertensives, cardiovascular agents, analgesics, steroids, physiologically active peptides and/or proteins, anti-cancer agents. antibiotics, fibrinolytics, anti-inflammatory agents, expectorants, muscle relaxants, epilepsy remedies, anti-ulcerative agents, anti-hyperchondriac agents, anti-allergic agents, diuretics diabetes curatives, hyperlipidemic remedies, anticoagulants, hemolytic agents, anti tubercular agents, hormones, anesthetic antagonists, osteoclastic suppressants, osteogenic promotives. angiogenesis suppressors, mydriatics, myotics, or glaucoma therapy and/or mixtures thereof The compositions as claimed in claim 1, wherein said pharmacoutically active ingredient is selected from anti-hypertensives, cardiovascular agents, analgesies, steroids, physiologically active peptides and / or proteins, anti-cancer agents, antibiotics, fibrinolytics, anti-inflammatory agents, expectorants, muscle relexants, epilepsy remedies, anti-ulcerative agents, anti-hyperchondriae agents, anti-allergie agents, diureties diabetes curatives, hyperlipidemie remedies, anticoagulants, hemolytic agents, anti-tubercular agents, hormones, anesthetic antagonists, osteoclastic suppressants, osteogenio promotives, angiogenesis suppressors, mydriatics, myotics, glaucoma therapy and or mixtures thereof.
- 4. (Currently amended) The pharmaceutical composition as claimed in claim 1, wherein the pharmaceutically active ingredient to poly(ethylene sebacate) ratio is in the range from 95:5 to 1:99The compositions as claimed in claim 1, wherein the drug to polymer ratio in said compositions is from 95:5 to 1:99.
- 5. (Cancelled)

044.P001 <u>Patent</u>

6. (Currently amended) The pharmaceutical composition as claimed in claim 1, wherein said drug delivery systems comprise molded implants The compositions as claimed in claims 1 to 4, wherein said drug delivery systems are molded implants containing drug.

- 7. (Currently amended) The pharmaceutical composition as claimed in claim 1, wherein said drug delivery systems comprise coated granules, prepared by coating the granules with 1-5% solution of said poly(ethylene sebacate) in a suitable solvent The compositions as claimed in claims 1 to 4, wherein said drug delivery systems are coated granules, prepared by coating the granules with 1-5% solution of said biodegradable aliphatic polyester in a suitable solvent.
- 8. (Currently amended) The pharmaceutical composition as claimed in claim 1, wherein said drug delivery systems comprise injectable microparticles suitable for sub-cutaneous, intramuscular, intravenous or periodontal administration. The compositions as claimed in claims 1 to 4, wherein said drug delivery systems are injectable sustained release microparticles suitable for sub-cutaneous, intra-muscular or periodontal administration for sustained action for the required period.

## 9. (Cancelled)

- 10. (Currently amended) The pharmaceutical composition as claimed in claim 1, wherein said drug delivery system comprises microparticles and/or nanoparticles dispersed in a gel formulation capable of periodontal administration. The compositions in the form of microparticles dispersed in gel as claimed in claims 1 to 4, wherein said drug delivery system in gel form is prepared by incorporating the micro particles in a gel suitable for the treatment of periodontitis.
- 11. (Currently amended) The pharmaceutical composition as claimed in claim 1, wherein said drug delivery system comprises film The compositions in the form of films as claimed in claims 1 to 4, wherein said drug delivery system is self supporting drug loaded films.

044.P001 Patent

- 12. (Currently amended) The pharmaceutical composition as claimed in claim 1The compositions in the form of microcapsule as claimed in claims 1 to 4, wherein said microcapsules comprise [[is ]]sustained release microcapsules.
- 13. (Currently amended) The pharmaceutical composition as claimed in claim 12The empositions as claimed in claim 12, wherein said microcapsules are can be produced in an oil/water suspension system, in which the drug is embedded within the polymer microparticles forming the oil phase, and stabilizing agents for the microparticles forming an the aqueous phase.
- 14. (Currently amended) The pharmaceutical composition as claimed in claim 13The emposition as claimed in claim 13, wherein the stabilizing agents comprise are selected from polyvinyl alcohol, polyvinyl pyrrolidone, alginate, gelatin, methyl cellulose, polyoxyethylene derivatives of sorbitan fatty esters and/or polyoxyethylene fatty ethers.
- 15. (Currently amended) The pharmaceutical composition of claim 1, wherein a particle size of said nanoparticles is in the range of 10 nanometers to 500 nanometers. The compositions as claimed in claims 12 to 14, wherein particle size of microparticles is in the range of 10 nm to 1000 microns depending on the type and concentration of stabilizer and drug to polymer ratio used in the formulation.
- 16. (Currently amended) The pharmaceutical composition as claimed in claim 1, wherein said drug delivery systems comprise lipase capable of modifying release of said pharmaceutically active ingredient The compositions as claimed in claims 1 to 15, wherein said drug delivery systems are with or without the addition of lipase to modify the drug release.
- 17. (Currently amended) The pharmaceutical composition as claimed in claim 1, wherein said pharmaceutical composition is capable of being administered by either oral, ophthalmic, parenteral, mucosal, or transdermal route The compositions as claimed in claims 1 to 16, wherein said pharmaceutical compositions could be administered by either oral, ophthalmic, parenteral, mucosal or transdermal route.

To: USPTO

044.P001 <u>Patent</u>

18. (Currently amended) The pharmaceutical composition as claimed in claim 1, further comprising [[P]]pharmaceutical compositions comprising at least one pharmaceutically active ingredient and biodegradable aliphatic polyesters derived from fatty diacids and fatty diols both with even number of carbon atoms; and particularly polyethylene sebaccate which is thermally stable, non-toxic, and metabolized by normal lipid metabolism in the form of different drug delivery systems as substantially described herein with reference to foregoing examples 1 to 18.